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10/070,587	07/10/2002	Leszek Wojnowski	VOS-30	7615

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EXAMINER

FETTEROLF, BRANDON J

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/070,587

Applicant(s)

WOJNOWSKI ET AL.

Examiner

Brandon J. Fetterolf, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 9-11, 14-36 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 12, 13, 37, 39 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: sequence comparison.

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Wojnowski et al.

DETAILED ACTION

Election/Restrictions

The Election filed on April 25, 2005 in response to the Restriction Requirement of 10/25/2004 has been entered. Applicant's election of Group 1, claims 1-8, 12-13, 37 and 39-40 in part, as specifically drawn to the special technical feature of a polynucleotide, vector, host cell and primer. Applicants have further elected from claim 1, SEQ ID NO: 90 as their invention. The Examiner acknowledges and agrees with Applicants assertion that a species election of claim 22 is not required at this time because claim 22 is not one of the elected groups.

Applicant's election with traverse of Group 1, Claims 1-8, 12-13, 37 and 39-40 is acknowledged. The traversal is on the grounds that Group 4, drawn to a transgenic non-human animal, and Group 4 [sic], drawn to a method of identifying and obtaining a CYP3A4 or CYP3A7 inhibitor by contacting a cell expressing a molecular variant CYP3A4 or CYP3A7 gene, should be examined together with Group 1, because a transgenic non-human animal of Group 4 and a cell of Group 4 [sic] expressing a protein variant are characterized by the nucleic acid sequence elected herein. Thus, Applicants conclude that no additional search is required. These arguments have been considered but are not found persuasive as such arguments do not apply when restriction is required under 35 USC 121 and 372, as in the instantly filed application. Thus, when the Office considers international applications as an International Searching Authority, as an International Preliminary Examining Authority, and during the national stage as a Designated or Elected Office under 35 U.S.C. 371, only PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111. Thus, it is maintained that the technical feature linking the inventions of Groups 1-11 does not constitute a special technical feature as defined by PCT Rule 13.2 and does not define a contribution over the prior art for the reasons of record.

Therefore, the restriction is deemed proper and made FINAL.

Claims 1-40 are currently pending

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Claims 9-11, 14-36 and 38 are withdrawn from consideration as being drawn to a non-elected invention.

Claims 1-8, 12-13, 37 and 39-40 are currently under consideration.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Applicant's claim for foreign priority under 35 U.S.C. 119(a-d) is acknowledged. After reviewing the EPO 991 18 120.7, for the disclosure of the nucleotide sequence set forth as SEQ ID NO: 90, the Examiner has established a priority date of **09/01/2000** (PCT/EP00/08570). If applicant disagrees with any rejection of claims 1-8, 12-13, 37 and 39-40 set forth in this office action based on examiner's establishment of a priority date of **September 01, 2000** for the instant claims in application serial number 10/070,587 applicant is invited to submit evidence pointing to the serial number, page and line where support can be found establishing an earlier priority date.

Information Disclosure Statement

The Information Disclosure Statement filed on 03/08/2002 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. A signed copy of the IDS is attached hereto.

In addition, the listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

The drawings filed on 04/08/2002, Figure 5b, are objected to under 37 CFR 1.83(a) because they fail to show which lines represent the wildtype and/or C1229G as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Applicants are reminded that no new matter should be introduced by amendment to the specification, see MPEP 35 USC 132.

Specification

The specification is objected to on pages 39 (Table 1), 41 (Table 2), 43 (Table 3), 44-45 (Table 4), Figures 4 and 6 for improper disclosure of nucleotide sequence without a respective sequence identifier, i.e. a SEQ ID NOs:. Hence, the disclosure fails to comply with the requirements of 37 CFR 1.821 through 1.825. In the absence of a sequence identifier for each sequence, Applicant must provide a computer readable form (CRF) copy of the sequence listing, an initial or substitute paper copy of the sequence listing, as well as any amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e-f) or 1.825(b) or 1.825(d).

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The disclosure is further objected to, page 32 (3rd paragraph), because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Applicants are reminded that no new matter should be introduced by amendment to the specification, see MPEP 35 USC 132.

Claim Objections

Claims 1-8, 12-13, 37 and 39-40 are objected to because of the following informalities: In addition to the elected SEQ ID NO: 90, Claim 1 recites non-elected nucleotide sequence identifiers and/or polynucleotides, which encode a CYP3A4 or CYP3A7 polypeptide. Claim 37 is further objected to as being dependent from a non-elected invention.

Appropriate correction is required.

Note: Claim 1 will be examined to the extent of a polynucleotide having the elected nucleic acid of SEQ ID NO: 90.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-2, 6 and 12, as written, do not sufficiently distinguish over polynucleotides and/or host cells, as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified" as taught, for example, by page 15 of the specification. See MPEP 2105.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-8, 12-13, 37 and 39-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-8, 12-13, 37 and 39-40 are rejected as vague and indefinite for reciting the term CYP3A4 or CYP3A7 as the sole means of identifying the claimed molecule. The use of laboratory designations only to identify a particular molecule renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct molecules. The rejection can be obviated by amending the claims to specifically and uniquely identify CYP3A4 or CYP3A7, for example, by SEQ ID NO. and function of CYP3A4 or CYP3A7.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-8, 12-13 and 39-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claims are inclusive of a genus of polynucleotides having the nucleic acid sequence of SEQ ID NO: 90 and/or any nucleotide deletion, addition and/or substitution thereof, wherein said polynucleotide encodes a genus of variant polypeptides and/or fragment therefore referred to as CYP3A4 or CYP3A7. However, the written description in this case does not appear to suggest any polypeptide, variant or fragment thereof, which is encoded by the polynucleotide having the nucleic acid sequence set forth in SEQ ID NO: 90, nor do the claims

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require that the polypeptide possess any particular biological activity, any particular conserved structure, or any other disclosed distinguishing features.

The specification teaches (page 12, 1st paragraph) that polynucleotides of the invention encode variant CYP3A4 or CYP3A7 proteins and/ or fragments thereof comprising one or more of the epitopes of the amino acid sequence encoded by SEQ ID NOs: 129, 135, 139, 145, 147, 149, 155, 158 or 160. The specification further teaches (page 12, 3rd paragraph) that amino acid deletion, addition or substitution in the amino acid sequence of the protein result from nucleotide substitution, insertion or deletion, wherein the preferred nucleotide substitution, insertion, or deletion results in an amino acid substitution of Gly56 to Asp, Arg130 to Gln, Val170 to Ile, Asp174 to His, Thr363 to Met, Leu373 to Phe or Pro416 to Leu in the CYP3A4 gene and/or Thr409 to Arg in Exon 11 of the CYP3A7 gene. Furthermore, the specification teaches (see sequence listing, SEQ ID NO: 90) that SEQ ID NO: 90 is made up of 1 nucleotides, which would encode a 3 amino acid residue. However, the written description does not appear to clearly suggest any polypeptide variant or fragment thereof, which is encoded by the polynucleotide having the nucleic acid sequence set forth in SEQ ID NO: 90 and/or any nucleotide substitution, deletion and/or addition thereof. A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common the genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cNDA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus."

The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus. That is, the specification provides neither a representative number of nucleotides that encompass the genus of polynucleotides having a nucleotide sequence of SEQ ID NO: 90 which encode a variant nor does it provide a description of structural features that are common to the genus. Further, the specification fails to provide a representative number of variant CYP3A4 or CYP3A7 proteins and/ or fragments that encompass the genus of polypeptide along with a description of structural features that are common to the

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genus. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure(s) of the encompassed genus of polynucleotides and proteins, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF’s were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, the written description not appear to clearly suggest any polypeptide, variant or fragment thereof, which is encoded by the polynucleotide having the nucleic acid sequence set forth in SEQ ID NO: 90 and/or any nucleotide substitution, deletion and/or addition thereof. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claims 6-8 and 39-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue

experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Applicants broadly claim a host cell genetically engineered with a polynucleotide having a nucleotide sequence of SEQ ID NO: 90 within a vector, a method for producing the said polypeptide by culturing the transgenic cell, a method of producing cells capable of expressing a molecular variant CYP3A4 or CYP3A7 gene comprising genetically engineering cells and a composition comprising the transgenic cell. These claims read on a cell within a transgenic animal given that the term "isolated" is not denoted in describing the transgenic cell. The breadth of the claim reads on the implementation of the transgenic cell in both *in vitro* and *in vivo* assays.

The state of the art at the time of filing was such that one of skill could not predict the phenotype of transgenics. For example, Overbeek (1994, "Factors affecting transgenic animal production," Transgenic animal technology, pages 96-98) taught that within one litter of transgenic mice, considerable variation in the level of transgene expression occurs between founder animals and causes different phenotypes (page 96, last paragraph). The art of transgenic animals has for many years stated that the unpredictability lies, in part, with the site or sites of transgene integration into the target genome and that "the position effect" as well as unidentified control elements are recognized to cause aberrant expression of a transgene (Wall, 1996 Theriogenology, Vol. 45, pp. 57-68). The elements of the particular construct used to make transgenic animals are also held to be critical, and they must be designed case by case without general rules to obtain good expression of a transgene; e.g., specific promoters, presence or absence of introns, etc. (Houdebine, 1994, J. Biotech. Vol. 34, pages 269-287, specifically page 281). Furthermore, transgenic animals are regarded to have within their cells, cellular mechanisms that prevent expression of the transgene, such as methylation

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or deletion from the genome (Kappell, 1992, Current Opinions in Biotechnology, Vol. 3, pp. 548-553).

Well-regulated transgene expression is not frequently achieved because of poor levels or the complete absence of expression or leaky expression in non-target tissues (Cameron, 1997, Molec. Biol. 7, pages 253-265, specifically page 256, col. 1 -2, bridg. parag.). Factors influencing low expression, or the lack thereof, are not affected by copy number and such effects are seen in lines of transgenic mice made with the same construct (Cameron, 1997, Molec. Biol. 7, page 256, lines 3-9). With regard to the importance of promoter selection, Niemann (1997) states that transgenic pigs made with different promoters regulating expression of a growth hormone gene give disparate phenotypes - one deleterious to the pig, the other compatible with pig health (Niemann, 1997, Transg. Res. 7, pages 73-75, specifically page 73, col. 2, parag. 2, line 12 to page 73, col. 1, line 4).

Examples in the literature aptly demonstrate that even closely related species carrying the same transgene construct can exhibit widely varying phenotypes. Mullins (1993, Hypertension, Vol. 22, pp. 630-633) states that not all animals express a transgene sufficiently to provide a model for a disease as the integration of a transgene into different species of animal has been reported to give divergent phenotypes. For example, several animal models of human diseases have relied on transgenic rats when the development of mouse models was not feasible. Mullins (1990, Nature, Vol. 344, 541-544) produced outbred Sprague-Dawley x WKY rats with hypertension caused by expression of a mouse *Ren-2* renin transgene. Hammer (1990, Cell, Vol. 63, 1099-1112) describes spontaneous inflammatory disease in inbred Fischer and Lewis rats expressing human class I major histocompatibility allele HLA-B27 and human β_2 -microglobulin transgenes. Both investigations were preceded by the failure to develop human disease-like symptoms in transgenic mice expressing the same transgenes that successfully caused the desired symptoms in transgenic rats (Mullins, 1989, EMBO J., vol. 8, pages 4065-4072; Taurog, 1988, Jour. Immunol., Vol. 141, pages 4020-4023). Mullins (1996, J. Clin. Invest. Vol. 98, pages S37-S40) disclose that the use of nonmurine species for transgenesis will continue to reflect the suitability of a particular species for the specific questions being addressed, bearing in mind that a given construct may react very differently from one species to another. Thus, at the time of filing, the phenotype of a transgenic cell contained within any animal was unpredictable and could not be prepared for any species. Applicants can obviate the instant

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rejection of Claims 6-8 by amending the claims to recite the term "isolated" before the recitation, "host cell".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4-6, 8, 12-13, 37, and 39-40 rejected under 35 U.S.C. 102(e) as being anticipated by Larossa et al. (U.S. 6,025,131, 1996).

Larossa et al. teach a polynucleotide having, from nucleotides 134 to 144, the presently claimed polynucleotide of SEQ ID NO: 90 (Columns 33 and 34, see attached sequence comparison for sequence identifier 12). The Patent further teaches (column 4, lines 53-55, column 11, lines 2-14, and Figure 1) a vector comprising the polynucleotide further operatively linked to an expression control sequence which allows for the expression in prokaryotic or eukaryotic cells. Moreover, Larossa et al. teach (page 4, lines 56-58) host cells with are genetically engineered with a vector comprising a polynucleotide operatively linked to an expression control sequence. Furthermore, the patent teaches (column 8, lines 60-67) a nucleic acid molecule which is complementary to the polynucleotide as the result of expression of the gene product, wherein the gene product is a protein. In addition, Larossa et al. (column 4, line 59 to column 5, line 2) provide a diagnostic composition comprising a probe useful for detecting chemical compounds, wherein said probe comprises a the polynucleotide operatively linked to a luminescent reporter gene complex. Lastly, the patent teaches a method for producing cells comprising genetically engineering cells with the polynucleotide (column 13, line 50 to column 14, line 34).

Therefore, NO claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF


GARY B. NICKOL, PH.D.
PRIMARY EXAMINER